K132325

5 510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for the GUIDOR® Bioresorbable Matrix Barrier 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: Sunstar Americas, Inc.
4635 W. Foster Avenue
Chicago, IL 60630

OCT 29 2013

Contact: M Squared Associates, Inc.
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Date of Submission: July 24, 2013

Proprietary Name: GUIDOR® Bioresorbable Matrix Barrier

Common Name: Barrier, Synthetic, Intraoral

Regulatory Class: Class II

Regulation: 21 CFR 872.3930

Product Codes: NPK

Predicate Device(s): Guidor™, Sunstar Suisse SA (originally submitted by Procordia OraTech AB) (K912724)
Resolut® Adapt LT Regenerative Membrane, WL Gore (K051267)
Inion GTR Biodegradable Membrane System, Inion Ltd (K033074)
Bio-Gide Resorbable Bilayer Membrane, Ed. Geistlich Soehne Ag Fuer Chemische Industrie (K050446)
Cytoplast™ Resorb, Osteogenics Biomedical, Inc. (K993610)
Ossix Plus, ColBar LifeScience Ltd. (K053260)

Device Description:

The GUIDOR® Bioresorbable Matrix Barrier is a two-layered (sandwich) structure with spacers between the layers that provide stability to the matrix and maintain an adequate space to aid in tissue regeneration

and prevention of epithelial downgrowth. The GUIDOR® Matrix is bioresorbable to allow for single-step surgery, eliminating the need for a second surgery to remove the matrix. This reduces the risk of infection and inflammation to the immature, regenerated tissue[1]. For guided bone regeneration (GBR), the GUIDOR® Bioresorbable Matrix Barrier is intended to aid in bone regeneration and augmentation, such as: extraction socket site preservation, immediate implant placement at time of extraction or delayed placement when additional bone regeneration is desired, ridge augmentation, sinus elevation, and function as a stable barrier for the containment of bone grafting materials.

When used for guided tissue regeneration, (GTR), the GUIDOR® Matrix is intended to aid in the regeneration and integration of periodontal tissue components. It is also for use as an adjunct in periodontal surgical treatment to supplement the reparative process following scaling and root planing for Class II furcations, intrabony defects, and recession type defects.

Indications for Use:

GBR Configurations

To aid in bone regeneration and augmentation in oral surgery for:

- Extraction socket site preservation
- Immediate implant placement at time of extraction or delayed placement when additional bone regeneration is desire,
- Ridge augmentation
- Sinus elevation
- Stable barrier for the containment of bone grafting materials

GTR Configurations

To aid in the regeneration and integration of periodontal tissue components. For use as an adjunct in periodontal surgical treatment to supplement the reparative process following scaling and root planning for:

- Class II furcations
- intrabony defects
- recession type defects

[1] Lundgren D, Mathisen T, Gottlow J. The development of a bioresorbable barrier for guided tissue regeneration. *J Swed Dent Assoc* 1994; 86:741-756.

Technological characteristics

The GUIDOR® Bioresorbable Matrix Barrier has the same technical characteristics and operating principles as the Guidor™ predicate (K912724). Both are composed of two layers, similar to the Inion GTR Biodegradable Membrane System (K033074), Bio-Gide Resorbable Bilayer Membrane (K050446), and Cytoplast™ Resorb (K993610) predicates which are all multi-layer products. The GUIDOR® Matrix Barrier is composed of synthetic materials similar to the Guidor™ predicate (K912724), Inion GTR Biodegradable Membrane System (K033074), and Resolut® Adapt LT Regenerative Membrane (K051267) predicates, while the remaining predicates are composed of collagen. The applicant and predicate devices have all been designed to be bioresorbable and sterile.

Summary of Nonclinical Testing

Performance testing is not necessary to support the proposed modifications to indications for use and instructions for use, as substantial equivalence of the device is demonstrated through the material properties and technical characteristics. Results of biocompatibility and sterility testing conclude that the GUIDOR® Bioresorbable Matrix Barrier is biologically safe for its intended use.

Summary of Clinical Testing

Results from retrospective clinical data and human studies reported in the literature for both synthetic resorbable membranes and resorbable collagen membranes support that the GUIDOR® Bioresorbable Matrix Barrier is substantially equivalent to those of the previously accepted and clinically successfully used bioresorbable membranes for similar indications.

Conclusion

The GUIDOR® Bioresorbable Matrix Barrier is as safe and effective as the predicate devices. The GUIDOR® Matrix Barrier has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. Therefore, the GUIDOR® Matrix Barrier is substantially equivalent to the predicate devices and may be used for guided bone regeneration (GBR), to aid in bone regeneration and augmentation, such as: extraction socket site preservation, immediate implant placement at time of extraction or delayed placement when additional bone regeneration is desired, ridge augmentation, sinus elevation, and function as a stable barrier for the containment of bone grafting materials. When used for guided tissue regeneration, (GTR), the GUIDOR® Matrix is intended to aid in the regeneration and integration of periodontal tissue components. It is also for use as an adjunct in periodontal surgical treatment to supplement the reparative process following scaling and root planing for Class II furcations, intrabony defects, and recession type defects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 29, 2013

Sunstar Americas, Incorporated
c/o Ms. Deborah Lavoie Grayeski
Regulatory Consultant
M Squared Associates, Incorporated
575 8th Avenue, Suite 1212
New York, New York 10018

Re: K132325
Trade/Device Name: GUIDOR® Bioresorbable Matrix Barrier
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPK
Dated: September 27, 2013
Received: September 30, 2013

Dear Ms. Grayeski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE STATEMENT

510(k) Number: To be assigned K132325

Device Name: GUIDOR® Bioresorbable Matrix Barrier

Indications for Use:

GBR Configurations

To aid in bone regeneration and augmentation in oral surgery for:
- Extraction socket site preservation
- Immediate implant placement at time of extraction or delayed placement when additional bone regeneration is desire,
- Ridge augmentation
- Sinus elevation
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- Class II furcations
- intrabony defects
- recession type defects

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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